

Response to First Office Action
Docket No. 020.0337.US.CONREMARKS

Claims 1, 17, 21, 22, 29, and 44 have been amended. No new matter has been entered. Claims 1-54 are pending and remain in the application.

Claims 17, 21, and 22 have been amended to correct clerical errors and not 5 for reasons relating to patentability or to overcome any grounds of rejection.

The Information Disclosure Statement mailed on July 21, 2005 was not acknowledged in the present Office action. This Information Disclosure Statement was timely filed and must be considered on the record. 37 C.F.R. 1.97(c). Acknowledgement of the foregoing Information Disclosure Statement 10 and entry of the cited art references are requested.

A further Information Disclosure Statement citing further art references is being submitted with this paper, along with payment of the appropriate fee. Acknowledgement of the further Information Disclosure Statement and entry of the cited art references on the record are requested.

15 Claims 1-54 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,168,563, to Brown ("Brown"). A claim is anticipated under 35 U.S.C. §102(e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131. Applicant traverses the rejection.

20 The Brown patent discloses a system and method that enables a healthcare provider to monitor and manage a health condition of a patient using a self-care health monitoring system (Abstract; Fig. 1; Col. 11, lines 22-23). In one embodiment, the system includes a computer server that is referred to as a clearinghouse computer facility and a remotely-programmable apparatus that is referred to as a data management unit. The server includes a script generator for generating a script program that is executable by the remotely programmable apparatus for interacting with an individual by asking the individual questions and providing information (Col. 9, lines 27-29 and 33-35). The server also includes a database that is connected to the script generator for use in storing the script 25 program and patient responses to queries communicated to the patient (Col. 9, 30

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lines 38-40). In an alternative embodiment, a user interface includes a speech synthesizer for audibly communicating the queries and a speech recognizer for receiving spoken responses to the queries (Col. 9, line 48-52).

At least one monitoring device produces measurements of a physiological condition of an individual, and the measurements are stored in a memory and transmitted to the server with responses to the queries (Col. 9, line 61 – Col. 10, line 2). A clearinghouse computer facility (server) facilitates communication between the individual and his or her healthcare professional, with a primary function of providing the healthcare professional with standardized reports via facsimile, which indicate both the current condition and condition trends of the individual (Col. 15, lines 5-11). Preferably, the data supplied to the clearinghouse consists of raw data that was stored in the memory of the data management unit (remotely programmable apparatus) without further processing (Col. 15, lines 44-49).

In one embodiment, a healthcare professional can operate a computer to access the data in the clearinghouse computing facility, which can be processed, analyzed, printed or displayed using commercially available or custom software (Col. 16, lines 32-42). Alternatively, various types of analyses may be performed by the clearinghouse computing facility with the results of the analyses being transmitted to the remotely-located healthcare professional (Col. 16, lines 42-45). In the preferred embodiment, a simple and inexpensive system for remotely monitoring children and young adults with diabetes is provided by using a Nintendo Gameboy to query the patient and to allow the patient to enter information and blood glucose measurements. The data is stored in the Gameboy cartridge and is provided to a healthcare provider via accessing the cartridge directly or a remote computer that receives data from the cartridge and transmits the data to the clearinghouse computer (Col. 5, lines 65-67, Col. 6, lines 1-2, 62-67, Col. 7, lines 1-67; Col. 8, lines 1-67).

Amended Claim 1 now recites a server periodically receiving a set of the collected measures retrieved on a substantially regular basis from the medical device, and analyzing one or more of the collected measures sets in the patient

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care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a patient status indicator of patient wellness to recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to determine whether medical intervention is necessary (emphasis added). Support for the amendments can be found in the specification on page 4, lines 25-29; and page 15, line 21-page 16, line 3.

Amended Claim 29 now recites analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a patient status indicator of patient wellness to recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to determine whether medical intervention is necessary (emphasis added). Support for the amendments can be found in the specification on page 4, lines 25-29; and page 15, line 21-page 16, line 3.

Amended Claim 44 now recites code for analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a patient status indicator of patient wellness to recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to determine whether medical intervention is necessary (emphasis added). Support for the amendments can be found in the specification on page 4, lines 25-29; and page 15, line 21-page 16, line 3.

Recognizing a trend and determining whether medical intervention is needed is significantly different than performing analyses and passively providing standardized reports to physicians, as taught by Brown. A trend indicates the occurrence of a change in the well-being of the patient and the trend can be in one of several possible directions that indicate disease onset, progression, regression, or status quo. Moreover, patient well-being is a holistic notion that embraces selecting a form of patient management appropriate to the individual patient or patient peer group, as well as determining what is wrong, or right, with a patient's

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health. As a result, determining whether medical intervention is necessary goes beyond indicating current condition and condition trends, without making a medical decision or suggestion, such as taught by Brown. Rather, an automated medical intervention determination, as recited by Claims 1, 29, and 44, requires 5 integrating multiple, possibly competing, diagnoses, to arrive at a medically sound decision on addressing the change in patient well-being. Thus, Brown only teaches providing data to a physician and does not teach or suggest taking action on the patient based on that data. Such limitations are neither taught nor suggested by Brown.

10 Claims 2-28 are dependent on Claim 1 and are patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 30-43 are dependent on Claim 29 and are patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 45- 15 54 are dependent on Claim 44 and are patentable for the above-stated reasons and as further distinguished by the limitations recited therein.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

20 Claims 1-54 are believed to be in condition for allowance. Entry of the foregoing amendments is requested and a Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any 15 questions or concerns associated with the present matter.

Respectfully submitted,

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